Proposal for Implementing Data Compensation Rights for Data Submitted in Support of Tolerance and Tolerance Exemption Actions

As part of the Food Quality Protection Act of 1996 (FQPA), Congress amended the Federal Food, Drug, and Cosmetic Act (FFDCA) to address exclusive use and compensation rights for data submitted to the Environmental Protection Agency (EPA) in support of tolerance and tolerance exemption actions, and to amend treatment of confidential information under the statute. On January 19, 2000, (65 FR 2947) EPA announced the availability for comment of a paper discussing options to enable the Agency to appropriately implement the new exclusive use and data compensation provisions contained in section 408(i) of the FFDCA. This paper discusses the comments received and sets forth a proposal which considers those comments and incorporates the Agency's concept of the implementation of a data compensation program under FFDCA section 408(i).[1] The paper also proposes an interpretation of the confidentiality provisions under 408(i). The Agency seeks public comment on this proposal.

I. Background

a. Registration of pesticides

EPA is responsible under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for registering pesticide products on the basis of scientific data or other information adequate to show that, among other things, the products will not pose unreasonable adverse effects on the environment. EPA may require that applicants and registrants submit data to the

[1] This paper does not address the issue of data that are "voluntarily submitted" to the Agency or the application of section 408(i) to import tolerance data submitted to support tolerances or tolerances exemptions.

Agency to assess whether a pesticide should be registered or continue to be registered. Persons wanting to obtain a registration for a pesticide product must submit an application package consisting of, among other things, information relating to the identity and composition of the product, and supporting data or a citation to supporting data.

FIFRA section 3(c)(1)(F) extends exclusive use or compensation rights to certain persons ("original data submitters") who submit data in support of an application for registration, reregistration, or experimental use permit, or to maintain an existing registration. Applicants who cite supporting data previously submitted to the Agency by the original data submitter must certify that an offer of compensation has been made to the original data submitter or that the submitter has granted permission to cite data. In the case of "exclusive use" data, the applicant must obtain the permission of the original data submitter and certify with the Agency that the applicant has obtained written authorization from the original data submitter. If an applicant or registrant fails to comply with these requirements, the application/registration is subject to denial or cancellation.

Since FIFRA places an obligation on the Agency to ensure that the original data submitter is offered compensation (or grants permission) for the use of data, a Pesticide Data Submitters List was developed to assist applicants in fulfilling their obligation. The Data Submitters List is a compilation of names and addresses of original data submitters who wish to be notified and offered compensation for use of their data. The Data Submitters List is available via the Internet at http://www.epa.gov/opppmsd1/DataSubmittersList.

b. Pesticide residue tolerances and exemptions

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For pesticides that may remain in or on food or animal feed, a maximum residue level (tolerance) must be established. In considering a tolerance action, EPA reviews certain types of data on a pesticide to determine if residue limits will be safe. Prior to passage of FQPA, FFDCA did not contain a data compensation and exclusive rights provision. Nonetheless, EPA has consistently taken the position that data submitted to support a tolerance or tolerance exemption are entitled to exclusive use or compensation if the data otherwise meet the requirements of section 3 of FIFRA. Specifically, the data must be submitted in support of a registration or reregistration action or must otherwise be submitted to support or maintain registration. Because most "tolerance-related" data are submitted to support registration actions, these data generally are subject to the compensation and exclusive use provisions of FIFRA.

II. Amendments to the Law

In 1996, Congress amended the FFDCA to add a new section 408(i) that explicitly addresses compensation and exclusive use rights for data submitted to support tolerances and tolerance exemptions. Congress provided that such data are entitled to exclusive use and compensation "to the same extent" provided in section 3 of FIFRA. However, the statute gives no further guidance as to whether this provision is simply intended to codify EPA's current practice, or whether Congress intended to expand data rights to those data that currently do not enjoy compensation or exclusive use rights. The pertinent part of the statutory language reads:

408(i) Confidentiality and Use of Data. –

(1) General rule.- Data and information that are or have been submitted to the

> Administrator under this section or section 409 in support of a tolerance or an exemption from a tolerance shall be entitled to confidential treatment for reasons of business confidentiality and to exclusive use and data compensation to the same extent provided by sections 3 and 10 of the Federal Insecticide, Fungicide, and Rodenticide Act.

EPA may receive data submitted in support of tolerance or tolerance exemption actions that are not submitted to support FIFRA registration actions. For example, data submitted by manufacturers of inert ingredients petitioning for the issuance of a tolerance or exemption and data submitted by persons petitioning for the issuance of a tolerance for a pesticide on imported food are generally not submitted in connection with any action under FIFRA. Under FIFRA such data would not, therefore, qualify for exclusive use or compensation status.

While the statute is silent on this matter, the legislative history in the House Committee on Commerce Report accompanying H.R. 1627 (the bill that was enacted as the FQPA of 1996) provides that "[t]he Committee intends that this section apply to data submitted to EPA prior to enactment, under old section 408 or 409, including data submitted under EPA guidelines by manufacturers of inert ingredients of pesticides" (H.R. No. 669, 104th Cong., 2nd Sess., pt 2, at 50, 1996). Since most data submitted by manufacturers of inert ingredients are not subject to protection under section 3 of FIFRA (because the data generally are not submitted in connection with a registration action), the legislative history suggests that Congress did intend to expand compensation and exclusive use rights to "tolerance" data that would not otherwise be entitled to protection under FIFRA.

III. Preliminary Options for Implementing Section 408(i)

On January 19, 2000, EPA solicited comments on three options put forth by the Agency to address implementation of the provisions of section 408(i) of FFDCA that relate to exclusive use and compensation rights. The three options presented were different interpretations of the potential scope of the new provision focusing on who the data submitters may be. Those options were:

A. *Option 1: Only Registrants and Applicants for Registration*

One approach to implementing section 408(i) would extend data compensation and exclusive use rights (data rights) only to those persons who submit data in support of tolerances or exemptions from tolerances that also meet all the conditions necessary to obtain such rights as set forth in section 3 of FIFRA. This option would read section 408(i) as Congressional ratification of the Agency's current treatment of "tolerance" related data. Therefore, under this option, data rights under section 408(i) would only extend to those persons who qualify as "applicants" under FIFRA for a current registration or reregistration action (See section 3(c)(1)(F) of FIFRA).

B. *Option 2: Any Person Who Submits Data Related to Current Registration/reregistration Action*

This reading of section 408(i), as in option 1, would extend data rights to those persons

who submit data in support of tolerances or exemptions from tolerances that also meet all the conditions necessary to obtain such rights as set forth in section 3 of FIFRA, the difference being that the submitter would not have to be an "applicant or registrant" as section 3(c)(1)(F)(iii) of FIFRA provides for data subject to the compensation provisions of FIFRA (as explained in section 1.B. above). This option would give some meaning to the FQPA legislative history that indicates that Congress intended to offer protection to data submitted by manufacturers of inert ingredients. It is unlikely, however, that this option would protect much data submitted by manufacturers of inert ingredients, since such data are rarely submitted for the specific purposes identified in FIFRA section 3 (registration, reregistration, etc.).

C. Option 3: Any Person Without Regard to Whether Data Relate to Current Registration or Reregistration

This reading of section 408(i) would extend data compensation and exclusive use rights to persons who submit data and who would otherwise qualify for data rights under both options 1 and 2 above. However, this option would also extend rights to data submitters without regard to whether the data submitted relates to any current registration or reregistration action or whether the data submitter is a pesticide registrant. Protections would only be linked to the issuance of tolerances and tolerance exemptions. This approach would likely extend protection to data submitted by manufacturers of inert ingredients. Because these individuals generally do not submit data in connection with pesticide registration activities under FIFRA, options 1 and 2 above would likely not provide the measure of data protection provided by this option.

IV. Summary of Comments Received

In response to EPA's solicitation for comment on the options noted above, EPA received comments from seven commenters.[2] Six of the seven commenters supported the development of Option 3, to expand data compensation and exclusive use rights to "Any Person Without Regard to Whether Data Relate to Current Registration or Reregistration." A variety of reasons were given for support of Option 3, including; 1) the expansion of data protection rights would encourage further development of inert ingredients; and 2) data protection should not rely on the registration process. One commenter, however, was concerned that the options did not contain a plan to enforce data protection rights and proposed a tiered scheme in which data protection was based on the value of the inert ingredient.

V. EPA Position

EPA believes implementing some form of option 3 gives meaning to 408(i) and provides some measure of equity to inert manufacturers who have paid and will pay money to conduct testing necessary to allow approval under both FIFRA and FFDCA. EPA believes it is

[2] See comments in Public Docket "OPP-00621A" located in the Public Information and Records Integrity Branch (PIRIB), Office of Pesticides Programs, Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Docket is open from 8:30 a.m. to 4:00 p.m., Monday through Friday, excluding federal holidays. The Docket telephone number is 703-305-5805.

appropriate to read 408(i) as establishing authority for EPA to use FIFRA as a guidepost for determining the nature and extent of protections that apply to data covered by 408(i). Thus, EPA has developed a proposal based on option 3 that provides a mechanism for protecting 408(i) data submissions.

VI. Scope of Proposal

a. Tolerance & tolerance exemption for inert ingredient data only

This proposal only addresses data protections for studies that have been and will be submitted to support tolerances or tolerance exemptions (i.e., food use data) on inert ingredients. FFDCA section 408(i) does not extend to data submitted solely to support non-food uses. To the extent that protections for non-food use data on inert ingredients exist, they would be found exclusively in FIFRA.

b. Initial listing and petition process

EPA believes there are approximately 8 to 10 inert ingredients for which EPA has received a significant amount of proprietary data from the manufacturer to establish a tolerance or tolerance exemption. Most of these tolerances or exemptions were established after the passage of the FQPA in 1996 and were therefore evaluated pursuant to the FQPA safety standard, as set forth in FFDCA section 408(b). EPA intends to address these inert ingredients in the initial phase of the proposed data compensation program for inert ingredients by inviting the data submitters of these inert ingredients to be listed on the data submitters list (DSL), which is currently used for active ingredients. The Agency acknowledges, however, that the protections of

408(i) are not limited to data submitted after the passage of the FQPA, and that there may be data submitters in addition to those identified in the initial phase of this program who have submitted to EPA data regarding inert ingredients that are protected under section 408(i). For this reason, any person who believes he or she has submitted proprietary data to support other tolerances or tolerance exemptions may petition the Agency to supplement the list of ingredients initially addressed by EPA.

c. Tolerance reassessment and inert data requirements

As required by section 408(q) of FFDCA, tolerances and tolerance exemptions established prior to the passage of FQPA are being reassessed under the new FFDCA section 408(b) safety standard, as described more fully in section VII of this document. EPA may require the submission of additional data in connection with reassessment determinations for inert ingredients. Section 3(c)(2)(B) of FIFRA and 408(f) of the FFDCA provide authority for the Agency to call in additional data needed for tolerance and tolerance exemption reassessment. EPA anticipates that the data call-in process would also provide the data compensation mechanism for data generated to address reassessment. EPA will also need to insure that applicants/registrants that register or amend products after the issuance of any such DCIs have satisfied these requirements. Accordingly, EPA will also make the section 408(i) data compensation program applicable to data submitted for new inert ingredients.

d. Confidentiality of 408 information

EPA also proposes to implement the revised confidentiality provisions in FFDCA section 408(i). Prior to the changes made in FFDCA by FQPA in 1996, confidentiality of information

submitted in support of a tolerance or exemption was governed by old section 408(f), which made all such information confidential until publication of a regulation establishing a tolerance or exemption (unless the submitter explicitly waived confidential protection). This section was replaced in 1996 by current section 408(i), which provides in part, "Data and information that are or have been submitted to the Administrator under this section or section 348 of this title in support of a tolerance or an exemption from a tolerance shall be entitled to confidential treatment for reasons of business confidentiality and to exclusive use and data compensation to the same extent provided by sections 3 and 10 of the Federal Insecticide, Fungicide, and Rodenticide Act." EPA has never formally interpreted the meaning of section 408(i) with respect to confidential information.

The likely intent of Congress was to accord information submitted in support of a tolerance or exemption the same confidentiality protections that apply to data submitted under FIFRA, especially considering the extent to which FIFRA and FFDCA were intertwined more closely by FQPA. Treating information submitted under the two statutes identically means that they are subject to the same protections *(e.g.,* restrictions on disclosure of entire studies to multinational corporations in accordance with FIFRA section 10(g)) and the same disclosure requirements (*e.g*., mandatory public availability of safety and efficacy information in accordance with FIFRA 10(d)(1)). In fact, this discussion may be largely academic, because EPA expects that nearly all data submitted under part 158 in support of a tolerance or exemption will also be information submitted under FIFRA. The only exception would pertain to import tolerances or exemptions for pesticides that are not used in the United States, submissions which are

uncommon. Therefore, EPA intends to apply FIFRA section 10 equally to data submitted pursuant to FFDCA 408.

VII. Procedural Matters

a. Process: What mechanisms will EPA use to implement section 408(i)?

While the implementation of section 408(i) necessarily requires EPA to interpret that provision, the statute does not require that EPA issue rules of general applicability through notice and comment rulemaking. Indeed, given that Congress gave immediate effect to 408(i) upon the enactment of the Food Quality Protection Act of 1996, it is apparent that Congress intended EPA to ensure protection of these rights in the absence of new rulemaking actions. Further, the actual determinations regarding the need for any individual applicant or registrant to cite data protected by section 408(i) are case-by-case decisions (informal adjudications) made in connection with individual registration actions and do not require the development of rules. Finally, given the pendency of reassessment activities for inert ingredients, EPA believes it is important to develop and implement this program on a schedule that will ensure protection of data that are being developed -- and that will be cited -- in connection with reassessment. For these reasons, EPA does not intend to develop its approach for implementing the exclusive use and data compensation provisions of section 408(i) through rulemaking.

Since new data compensation programs will be integrated into a part of the existing registration process, some additional changes will likely need to be made to the process to ensure protection of data on inert ingredients. Specifically, EPA is evaluating the extent to which

Pesticide Registration Notice (PRN) 98-10, (Notifications, Non-Notifications and Minor Formulation Amendments, October 22, 1998) should be amended to ensure protection of rights in inert ingredient data. Under this current EPA policy, registrants are in certain instances permitted to change suppliers of inert ingredients by either "notification" or "non-notification" rather than full amendment. Because only the full amendment process includes the submission and review of data or data compensation materials, notification and non-notification procedures cannot be used for a change in inert ingredient suppliers if data must be submitted or cited for the ingredient. Likewise, EPA will be reviewing for potential modification PRN 98-5, (New forms for the Certification with Respect to Citation of Data and EPA form 8570-34, June 12, 1998); and the Formulator's Exemption Statement, EPA form 8570-27. EPA is considering modifications to the language to provide for data submitted under section 408(i). EPA seeks public comments on whether any other PRNs or forms should be modified and reasons why.

b. Incorporating FFDCA section 408(i) data protection into the FIFRA process

Currently, the obligation to satisfy any inert ingredient data submission and compensation requirement is part of an applicant's obligation to submit or cite data in connection with FIFRA registration activities. EPA does not believe section 408(i) either mandates or creates an alternate vehicle for protecting the additional data rights created by that section. Indeed, the FFDCA provides no mechanism for ensuring protection of the rights provided by 408(i). Further, EPA has no authority under FIFRA or the FFDCA to develop a distinct inert ingredient licensing scheme similar to that provided by FIFRA for registration of pesticide products, that would allow EPA to ensure protection of rights in such data separate and apart from the registration of

pesticide products that contain these ingredients. For this reason, EPA believes Congress intended the Agency to use the FIFRA registration process to protect FFDCA section 408(i) data rights.

c. Citing data and the formulator's exemption

Under FIFRA, applicants must satisfy applicable EPA data requirements at the time of registration or amended registration by either submitting data or citing to data in EPA's files that have previously been submitted by another person. In some instances, applicants may be exempt from certain data requirements if they purchase registered source materials (the "formulator's exemption"). When applicants cite data, they generally must either obtain the permission of the data submitter to cite the data, or they must offer compensation to the data submitter. EPA believes this obligation to submit or cite data also extends to data protected by section 408(i), and that EPA's existing data submission/data compensation system can be tailored to insure protection of these rights. Accordingly, applicants and registrants whose pesticide products contain an inert ingredient addressed by this initial program will be required to satisfy applicable data requirements for that ingredient prior to registration or amended registration. EPA also believes that the principles underlying the formulator's exemption (i.e., that the purchase price includes data development costs) can also be extended to inert ingredient data. Thus, EPA believes that inert ingredient data requirements can also be satisfied if the applicant can demonstrate and certify that its supplier (or the person or persons from whom its supplier obtained the ingredient) has already submitted the required data to EPA.

d. Data requirements

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While EPA has not by regulation established a generic set of data requirements for inert ingredients (although the Agency recently proposed a paradigm for evaluating inert ingredients that involves tiered data requirements depending upon what is known about the hazard of the ingredient, 67 FR 40732, June 13, 2002; http://www.epa.gov/oppfead1/cb/csb_page/updates/lowertox.pdf), EPA believes that section 408(i), like FIFRA, extends protections to data that EPA requires to support new or existing tolerance and exemption activities regardless of whether EPA has an established set of data submission guidelines. Because tolerance and tolerance exemptions must be issued prior to registration for any ingredient that may result in residues in or on food, any data that are needed for EPA to evaluate and issue appropriate tolerances or tolerance exemptions are "required" data that must be submitted or cited by applicants. Therefore, section 408(i) similarly protects rights for data submitted on new inert ingredients that are necessary for the establishment of a new or existing tolerance or tolerance exemption even though EPA has not established a formal set of requirements for such data.

e. Modification of the Data Submitters List (DSL)

EPA intends to expand the existing data submitters list (DSL) to include the names of the inert ingredient data submitters who have submitted data to support tolerance/tolerance exemptions for the ingredients addressed in the initial program. As with the existing DSL, applicants and registrants will be able to contact persons on the list to make the appropriate offers of compensation or otherwise obtain permission in order to cite these data. Applicants with products that include any inert ingredient listed on the DSL will need to indicate on the required

data compensation form that is submitted to EPA the manner in which the applicant or registrant has satisfied requirements for such inert ingredients as well as the existing requirements for the active ingredients and any product specific data requirements.

f. What measure of protection do the data receive?

As articulated above, EPA believes the best and most fair reading of section 408(i) expresses Congressional intent that EPA use section 3 of FIFRA as a guidepost for determining both the extent of protection and the procedural events to initiate protection of 408(i) data. Thus, the FIFRA 10-year "exclusive use" and 15-year "compensation" periods apply to inert ingredient data submitted in support of a tolerance or tolerance exemption.

The more difficult matter is determining precisely which data the "exclusive use" period applies to, and which data are subject only to "compensation" rights. Under section 3 of FIFRA, data submitted to support the initial registration (and any new use) of a product containing a new active are entitled to "exclusive use" treatment for a period of 10 years following the initial registration of the pesticide. During this period, applicants for registration may not cite these data to satisfy EPA data requirements without the permission of the original data submitter. As a general matter, all other data submitted by an applicant or registrant to support or maintain the registration of a pesticide are entitled to 15 years of "compensation" protection following the submission of the data. During this period, applicants may not cite such data in support of registration or reregistration activities without first offering compensation to the original data submitter. A comparable and consistent application of the principles of FIFRA section 3(C)(1)(F) would be to provide exclusive use protection to data submitted to establish the first tolerance or

tolerance exemption for an inert ingredient for the 10-year period following the issuance of the tolerance or exemption, and to provide compensation rights for all data submitted to support or maintain a tolerance for the 15-year period following the date of submission of the data. EPA believes that the mandatory arbitration clauses will also apply. EPA believes extending these provisions to section 408(i) data submittals would provide "to the same extent" the data protection rights afforded under section 3 of FIFRA. EPA would like to receive comment on this interpretation of section 3(C)(1)(F) of and its potential applicability to 408(i) data.

VIII. Tolerance Reassessment Activities for Inert Ingredients

EPA envisions that the section 408(i) data compensation program will be expanded through tolerance reassessment as EPA identifies potential additional data needs to meet the requirements of Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996. Under section 408(q), EPA is required to reassess all tolerances and exemptions for both active and inert ingredients that were in effect prior to the enactment of the FQPA At that time, over 850 tolerance actions involving inert ingredients were subject to tolerance reassessment.

EPA envisions that section 408(i) data compensation activities will be tied to tolerance reassessment in order of the priority established by EPA. Section 3(c)(2)(B) of FIFRA and 408(f) of the FFDCA provide authority for the Agency to call in additional data needed for tolerance and tolerance exemption reassessment. EPA anticipates that the data call-in process would also provide the data compensation mechanism for data generated to address reassessment. Thus,

EPA will at that time expand this program to ensure that EPA protects rights in inert ingredient data that flow from compliance with any DCI issued. After the issuance of any such DCIs, EPA will also need to insure that applicants for registration or amended registration under FIFRA have satisfied these requirements.

IX. Submitting Comments

EPA specifically solicits public comments on the proposal described in this paper. Comments submitted on other alternative methods of implementing section 408(i) will also be considered. For additional information or instructions on how to submit comments please refer to the related Notice of Availability in E-Docket No. OPP-2002-0296.